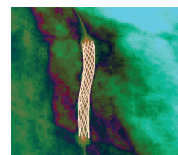


Challenges in Evaluating and Standardizing Medical Devices in Health Care Facilities

C. Lee Ventola, MS



Introduction

Recent decades have witnessed major advances in medical technologies that have been responsible for earlier and more accurate diagnoses, more effective treatments, and the ability of people to live longer, healthier lives.^{1,2} But because new technology is the primary driver of rapidly rising health care expenditures, these advances do not come without a cost. Therefore, a careful evaluation of drugs, supplies, equipment, and even discharge criteria is increasingly necessary in clinical practice.³

In an effort to control costs, health care facilities are now being more selective in how they evaluate and purchase medical devices. Although safety was previously the primary concern, there is now a growing demand for data on efficacy and cost effectiveness to enable this selectivity. However, a number of obstacles prevent medical devices from undergoing the standard formulary committee review process that is applied to drugs. Value analysis teams, payment caps, and group purchasing organizations are alternative means by which the merits of medical devices can be evaluated and by which costs can be controlled.

Hospitals Pressured by Escalating Supply Costs

Supply costs are a major area where hospital expenditures are escalating.⁴ Hospital executives frequently rank increased costs and pricing pressures as their primary concerns.⁵ The average hospital's supply costs grew by nearly 40% in the two years from 2003 to 2005 to more than \$50.5 million.⁴ This problem is exacerbated by the disproportionate constraint of health insurance reimbursements.⁵ For example, between 1991 and 2004 the cost of orthopedic implant devices rose by 132%, whereas hospital reimbursement rose by only 16%.⁵ The problem of rising costs is further compounded by the growing demand for procedures for which medical devices are required. According to the National Center for Health Statistics (NCHS), knee replacements increased by 40% between 2000 and 2004 and are expected to expand by another 673% by the year 2030.⁴

Hospitals are therefore increasingly aware that choice of medical device, based solely on safety or physician preference, is no longer adequate and that cost effectiveness is also critical. Christine Maroulis, Director, Health Economics and Reimbursement, Ethicon Women's Health and Urology, a division of Ethicon, Inc., a Johnson & Johnson company, observed, "As hospital revenues have been constrained and reimbursements have decreased, hospitals are looking everywhere to find savings, so we've definitely witnessed this change in our customer's perspective over the last few years."

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Accepted for publication April 27, 2008.

Establishing a Formulary for Medical Devices Via P&T Committee Review: Is It Feasible?

Unfortunately, the application of a formulary committee review to medical devices might not be as straightforward or feasible as it is for drugs. Dr. Randy Vogenberg, RPh, PhD, Chief Strategic Officer of Employer-Based Pharmaceutical Strategies and Adjunct Assistant Professor of Pharmacy Management at the University of Rhode Island, noted that "with drugs, very clearly the P&T committee is the final decision maker but [it is] generally not the final decision maker for medical devices."

The standard responsibility of formulary committees is to provide the clinical judgment of physicians, pharmacists, other specialists, and sometimes advisory subcommittees involved with the selection and use of drugs within health care organizations.^{6,7} Pharmacy and therapeutics (P&T) committees assess drugs according to efficacy, safety, outcomes, and relative costs⁴ and establish policies for drug access and administration.⁶ During the formulary review process, balancing costs and health outcomes is critical, and the use of commonly available data is necessary to do so.⁷ The result of a P&T committee review is a hospital formulary that specifies permitted drugs and drug categories and medications available only by exception.⁴ Formularies must be continually updated so that they remain current with advances in medicine and with the launch of new products.⁶

"... the P&T committee is the final decision maker [for drugs], but [it is] generally not the final decision maker for medical devices."

Although the P&T committee model has been a successful approach to drug standardization, there are inherent obstacles to applying this process to medical devices.⁴ Throughout the health care system, from health plans to hospitals, formulary committees for pharmaceuticals have few correlates in the coverage of devices.⁸ Dr. Vogenberg explained:

Typically, a P&T committee doesn't get directly involved in reviewing medical devices but may be advisory to a surgical or medical supplies committee. A P&T committee would get involved only in a secondary or tertiary role to make sure medical device authorizations coordinate with everything else that is going on in a hospital. The absolute final decision would be by the medical executive committee in a hospital.

One obstacle to the creation of a medical device review process by a P&T committee is that fewer clinical trial data are

Disclosure: The author has no commercial or financial relationships to disclose in regard to this article.

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available on therapeutic equivalencies and treatment outcomes for medical devices than for pharmaceuticals.⁴ In addition, because Food and Drug Administration (FDA) requirements for long-term safety and efficacy can be less stringent for medical devices, a new device is brought to market much more rapidly, making it difficult for hospitals and other institutions to stay current.⁴ Assessment of product equivalencies for items with different features developed by diverse manufacturers is also problematic.⁴ Cost comparisons or effectiveness evaluations are not always possible because manufacturers rarely reveal pricing voluntarily.⁴ Dr. David Nash, MD, MBA, Professor and Chair of the Department of Health Policy at Jefferson Medical College, agreed: “Pricing is largely hidden from the public analysis process, especially when you factor in rebates, discounts, and all kinds of separate payment schemes.”

Unlike the situation with drugs, it is also far more difficult to substitute an alternative surgical implant if a patient does not respond well to the one specified by a formulary.⁴ Limitations in the choice of manufacturer or device for a given medical procedure might also not be desirable, because surgeons often need to customize their selection according to specific patient needs and their surgical training experience.⁹

Manufacturers rarely reveal pricing voluntarily. ... “Pricing is largely hidden from the public analysis process, especially when you factor in rebates, discounts, and all kinds of separate payment schemes.”

Similar to what caused the Joint Commission on Accreditation of Hospitals (JCAH [now known as the JCAHO]) to recommend the formation of P&T committees to review drugs in the 1950s,⁶ advances in technology have led to an onslaught of medical devices reaching market and thus an increased need for evaluation. However, because of the obstacles mentioned, P&T committees rarely evaluate medical devices. Instead, an *ad hoc* team effort is made through the coordination of expertise from various departments, depending on the device.¹⁰

This process varies by hospital. According to Dr. Vogenberg, “You get variations depending on the sophistication of the hospital and the organization and how many committees they have.” Dr. Nash also explained:

Our P&T committee is very large, with a number of super-specialized subcommittees. There is no dedicated device subcommittee, so we draw on the specialties of our other subcommittees. We will likely evolve into having permanent experts, but it would be hard to mandate, because there aren't enough experts out there.

The decision-making process for medical devices is highly complex and subject to many constraints (e.g., surgeon's choice, vendor pricing, and time pressures).¹⁰ Group decision-making is necessary, because it provides expertise and achieves goals that are beyond the range of one single individual.¹⁰ Dr. Nash agreed: “There isn't a single person with the complete skill set for device evaluation.” Some new technologies also affect therapeutic decisions in multiple areas.

Dr. Vogenberg noted: “There is more demand for interrela-

tionship, intercommittee, and interdepartmental discussion about what's the best way to deal with new technologies. It's a newer scenario and something that hospitals, as well as health plans and Medicaid, are just beginning to come to grips with.”

The decision-making process for medical devices is highly complex and subject to many constraints.

The FDA's Medical Device Review Process

The FDA's regulatory policy is largely responsible for the rapid introduction, as well as the large quantity, of medical devices coming to market and the lack of clinical data for the majority of them. The growth of medical technology has been explosive.⁸ According to FDA estimates, more than 8,000 new medical devices are marketed each year in the U.S.¹ By the late 1990s, the FDA had approved about 500,000 medical device models produced by approximately 23,000 different manufacturers.⁸

Within the FDA, the Center for Devices and Radiological Health (CDRH) is responsible for premarket assessment of medical technologies,⁸ good manufacturing process guidelines, and postmarket surveillance (Figure 1).¹ However, the premarket evaluation of most medical devices by the FDA, before their introduction to the market, is not as thorough as it is for drugs.⁸ Whereas all new drugs must undergo rigorous premarketing testing in randomized clinical trials to receive FDA approval, such testing is required for relatively few new devices.⁸ Instead, the FDA regulates new devices according to classification as low risk (I), moderate risk (II), or high risk (III).⁸ Half of the medical devices marketed each year are considered to be *low-risk* products (bandages, splints, and surgical drapes), and these are exempt from all premarket review requirements.¹

Most of the remaining new products are iterations that have undergone an incremental change made to a previously marketed version; the FDA classifies these incremental products as having a *medium risk*.¹ Such products include endoscopes, patient-monitoring equipment, dialysis catheters, and diagnostic imaging devices (computed tomography, magnetic resonance imaging, and ultrasound scanners).¹ For these products, the FDA requires only a premarket notification application (510k), because they are assumed to be essentially equivalent to those already approved.⁸ Alan Minsk, Esq., Partner and Chair of the Food and Drug Practice Team at the Arnall Golden Gregory law firm, noted, “Most devices go through a 510k premarket notification process where you provide notice to the FDA that your product is substantially equivalent to a product they've already seen.”

The 510k medical device application process does not usually require clinical data from randomized efficacy and safety trials, and many devices, therefore, are approved on the basis of limited data.⁸ Alan Minsk also observed, “About 95% to 98% of the products on the market take the 510k route, where clinical trials aren't required. There are safety and efficacy standards, but they aren't going through the same level of review as drugs.”

In contrast to the 510k process, a premarket approval (PMA) application and formal clinical trials are required for novel

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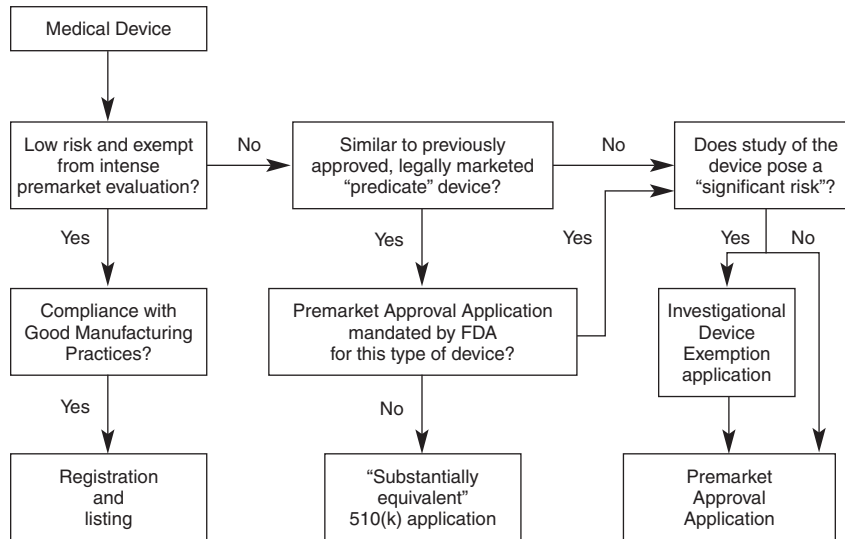


Figure 1 Overview of the medical device approval process. (Reproduced with permission from Maisel WH. *Ann Intern Med* 2004;140:297. American College of Physicians.)

technologies that the FDA has never seen before because they are considered *high risk*.⁸ A more stringent review process that calls for clinical trials is also undertaken for high-risk iterative medical devices, such as pacemakers, heart valves, and implantable pumps, as well as for those that have new indications for use or have changed significantly from the predicate device.¹

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The FDA's resources, abilities, and policies regarding medical devices are sometimes considered inadequate. Because clinical trial testing is not required for most medical devices, new products are rapidly approved, have an increasingly compressed life cycle, and become obsolete more quickly.¹¹ According to Alan Minsk, "the 510k process typically only takes anywhere from three to nine months, depending on whether clinical data are required, how well the submission is done, and the workload of the agency."

Sheri Dodd, Vice President Worldwide, Health Economics and Reimbursement at Ethicon, Inc., a Johnson & Johnson company, noted that within "six months, you can have five new entries to the market, because the regulatory pathway for a 510k process is the 'lowest bar.' There are many devices in the marketplace that have been subjected to appropriate pre-clinical testing, but not in humans, which is a very different model [than] pharma."

The volume of applications for new products being introduced to the market also creates a challenge for the FDA, as well as for hospital committees, to keep current. The FDA has warned of a lack of program resources for medical devices. The agency has stated that these resources "have been reduced in

recent years, and there have been indications that review performance has begun to decline."⁸ The FDA has limited ability to conduct postmarketing surveillance for both medical devices and drugs.⁸ Instead, manufacturers, academic staffs, and clinical investigators initiate most of the recalls and failure reports.⁸ The FDA has also had to recall a number of previously approved devices.¹² Because of these recalls, some wonder whether medical devices are being appropriately scrutinized by the FDA prior to approval.¹²

Data to Support Evidence-Based Decisions Are Lacking

The lack of clinical data available to medical device review committees in hospitals is largely attributable to the fact that the FDA's application process for most medical devices does not require such information. Because the data are not required, manufacturers have little incentive to conduct studies needed to answer relevant clinical questions.⁸ Dr. Nash commented, "There's not enough published literature to rely on. It doesn't exist because there is no compelling reason. Without an FDA mandate, no device manufacturer is going to undertake a rigorous evaluation."

Significant gaps also persist in postmarketing surveillance data.⁸ A lack of clinical data also puts insurance reimbursement in question, because evidence of efficacy is often required for determining payer coverage and reimbursement.¹ In addition, when the FDA requires clinical data, insurers may find the study endpoints to be insufficient.¹ Insurers, therefore, often have incomplete information when a new medical device is first marketed, and conclusive evidence is often available only after the device has been in use for quite a while.¹ Instead of being guided by clinical data, the evaluation and use of medical devices are often significantly influenced by industry and professional societies.⁸

Hospital review committee staff members are aware of the critical role of accurate data to support decisions about prod-

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uct use and equivalencies, cost comparisons, and the evaluation of patient outcomes.⁴ An evidence-based approach enables health care to be informed and tailored by scientific methodology.⁸ Safety and efficacy are enhanced when clinical practice is guided by well-designed, randomized, controlled, multicenter clinical trials.⁸ Decisions based upon scientific evidence also increase transparency and potentially reduce bias and conflict of interest.⁸

However, most facilities do not have the ability to conduct their own analyses, because conventional computer systems lack the ability to track products by specific identification numbers, costs, and outcomes.⁴ Although some dedicated information systems are designed specifically for medical devices in areas such as cardiology, the enterprise software systems that hospitals generally use do not integrate cost and clinical data needed to determine equivalencies.⁴ Many facilities maintain a clinical effectiveness database that includes length of stay and morbidity, but the data are not tied to specific products.⁴ Some manufacturers also obscure data needed for cost comparisons and even include a price disclosure confidentiality clause in their contracts with hospitals.⁴

An additional problem is that the evidence-based technology assessments that are available are poorly disseminated.⁸ Several independent medical technology assessment groups in the U.S., as well as abroad, maintain critical analyses of the efficacy and safety of new medical devices. Recently, an initiative was proposed in the U.S. for the formation of a national database of comparative data for prices and quality outcomes for devices in the same category.^{2,8}

The entire medical community—clinicians, patients, administrators, and manufacturers—would also benefit from better access to evidence-based technology assessments like those provided by independent groups such as the Technology Evaluation Center of the Blue Cross–Blue Shield Association (TEC) and the California Technology Assessment Forum–Blue Shield of California Foundation (CTAF).⁸ In the United Kingdom, the National Institute for Health and Clinical Excellence (NICE) evaluates devices according to the same protocol that it applies to drugs.⁸ A European Cardiac Surgery database also provides clinical outcomes and benchmarking capabilities for medical devices.⁹ These evidence-based assessments instill confidence in the efficacy of new products and procedures, provide points of differentiation, and influence practice.^{8,9}

Hospital committees are increasingly demanding proof that newer, costlier drugs or medical devices are more effective and efficient than existing products, cause fewer adverse effects, and reduce health care expenses; consequently, postmarketing studies will likely assume greater importance in the future.³ Dr. Nash remarked:

The same rigorous evidence-based analysis is now being applied to devices as has been historically done with new drugs. Device manufacturers are going to be increasingly put upon to provide information beyond efficacy, such as cost-effectiveness and cost-benefit information, and clinical data from randomized trials. Previously, devices had to satisfy an analysis only for safety, but now they will be evaluated on the basis of efficacy, efficiency, and effectiveness. The expense of these products has now mandated a more thorough evaluation.

Sheri Dodd agreed, noting:

Our customers are starting to ask what the value is, even for products at the 510k level. We are starting to generate premarketing and postmarketing clinical evidence that otherwise wouldn't be required for FDA approval but is for what we are calling 'market access approval,' an approval by our purchasing customers. We have evidence-generation strategies for all our products, so we are providing input early rather than having a negative P&T committee review due to insufficient data."

The relatively new field of pharmacoeconomics has also emphasized cost-effectiveness analyses that consider both direct and indirect costs of newer drugs and therapeutic modalities.³

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Current Procedural Terminology (CPT®) Codes And Reimbursement for Medical Devices

Reimbursement policies are important because they shape medical practice.¹ Because few patients are able to pay for health care directly, third-party payers play an influential role in determining how new medical technology is used.¹ Medical device manufacturers depend on insurance reimbursement to create favorable conditions for selling their products.¹ Christine Maroulis explained: "With the introduction of a new device, we are often creating entirely new medical procedures that require the establishment of new codes, new coverage policies, and new payment methodologies." Health care providers and institutions depend on reimbursement to offset the costs of adopting new products and procedures into medical practice.¹ Reimbursement policies consequently serve as an influential gatekeeper for new medical technologies and procedures.¹³ They also have become an area of conflict between the adoption of these new products and procedures and the control of health care and insurance costs.¹³ The current reimbursement climate presents daunting challenges for health care practitioners and institutions.¹

The influence of Medicare's reimbursement policies is widespread, because they extend to private payers who use these payment rates as a benchmark for setting their own rates.¹⁴ Medicare is the largest purchaser of health care services in the U.S., providing health insurance coverage for more than 41 million people and accounting for 20% of all health care spending.¹⁴ In the Medicare system, prices are set prospectively by the Centers for Medicare and Medicaid Services (CMS).^{13,14} Private payers typically pay a certain percentage above the Medicare price, and public programs, such as Medicaid, pay some percentage below it.¹⁴

However, the determination of reimbursement policies by Medicare is often delayed. A study by the Lewin Group found that it took the CMS from 15 months to five or more years to add new medical technologies to the Medicare program.¹ This

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presents a reimbursement hurdle for practitioners and manufacturers, because most medical devices have life spans of only 12 to 18 months.¹ Efforts are currently under way at the CMS to accelerate this process; however, the current situation impedes medical device innovation, involves high compliance costs, and delays patient access to technologies that have already been cleared by the FDA.¹

Reimbursement for new technologies is also dependent on the assignment of proper codes. However, assignment of Category 1 Current Procedural Terminology (CPT) codes by the American Medical Association requires the existence of published peer-reviewed clinical studies as well as widespread use of the new technology or procedure.¹ This standard increases the time it takes to establish a new code and raises reimbursement uncertainties for manufacturers and health practitioners for devices that clear the FDA under the 510k process without efficacy data.¹ In addition, to acquire a Healthcare Common Procedure Coding System (HCPCS) code, coding applications for medical devices may be made only after the accumulation of three months of market experience.¹ A new device, therefore, has to be marketed and sold without the necessary code for billing purposes and, consequently, with questionable prospects for coverage and payment.¹

Health care practitioners are discouraged from using new technology if it has not been assigned a code and an appropriate reimbursement amount.¹ New codes also motivate insurers to consider whether the new procedure should be covered—and if it is covered, to spell out whether the coverage is limited in terms of patient indications, sites of care, or qualified providers.¹ These are difficult decisions, even when a rich body of evidence about the impact of new technology on health outcomes is available.¹ A relatively new option available since 2006 is the assignment of Category III CPT codes to identify and track new technologies to accumulate required data and to provide evidence of widespread use.¹ Unfortunately, however, some payers view Category III CPT codes as indicating an investigational or experimental procedure for which payment is usually denied, even though the CPT committee has stated that these codes should not be interpreted in this way.¹ During 2005, a Category I miscellaneous code was recommended for billing for new medical technologies.¹ Some local Medicare contractors chose to cover these procedures despite the lack of a specific code.¹ However, some private payers have ruled that both Category III CPT codes and Category I miscellaneous codes indicate “the evidence is insufficient” and that the device is not covered because it is perceived as experimental or investigational.¹ Because Category III codes tend to flag new technologies, possibly leading insurers to deny coverage and payment, practitioners and manufacturers need to carefully consider the possible reimbursement consequences of a Category III code assignment.¹

Hospitals may also be eligible for special “pass-through” payments for using a new technology in hospital outpatient settings that is identified by another type of code: an HCPCS Level 2 temporary national code issued by the CMS, known as a *C code*.¹ The C code serves the same purpose as a Category III CPT code, in that it identifies new device procedures.¹ The CMS has used these temporary HCPCS codes to facilitate complete hospital reporting of their charges for medical

devices.¹

The majority of new medical devices that come to market each year do not raise billing-code coverage or payment questions.¹ Most of these technologies fit within coding and payment categories that have already been established, or they are similar to existing items for which coverage determinations have already been made.¹ However, reimbursement plays an extremely important role when new devices—or the procedures associated with their use—do not fall within existing insurance categories, when they are used in new ways or for new indications, or when they attract attention because of their cost.¹ In these situations, new codes may be needed to distinguish these devices from previous technology, and the process of securing them can be both lengthy and complex.¹ Manufacturers must be aware of the reimbursement environment for the new technologies they develop.¹

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Generation of Postmarketing Surveillance Data Complicated by Reimbursement Codes

Since the early 1980s, Medicare has provided bundled payments to hospitals for inpatient procedures based on more than 500 distinct Diagnosis-Related Groups (DRGs) that classify each discharge.¹⁴ A specific fixed rate of payment is set for each DRG.¹⁴ The DRG payment system is based on International Classification of Disease, 9th Revision (ICD-9) codes, which are used to identify the surgical procedures performed.¹⁴ Device manufacturers need to review existing ICD-9 codes to ensure that they are sufficient to describe procedures involving new technology and, if not, seek new DRG assignments.

For hospital outpatient procedures, Medicare requires CPT codes instead of ICD-9 codes.¹ Medicare groups these CPT codes into various payment bundles, called ambulatory payment classifications (APCs), for which a specific rate of payment is also set.¹ Fixed-rate payments by Medicare under a DRG or an APC bundle to hospitals serve as reimbursement for the technical component of services.¹⁴ Bundled DRG or APC payments lack a distinct code that identifies medical devices, making it difficult to conduct the postmarketing surveillance necessary to build a database to support evidence-based decisions about patient outcomes and cost effectiveness.

Christine Maroulis commented:

When you are talking about a surgery, an ICD-9 code for diagnosis and for payment procedure is noted and tracked with an appropriate MS-DRG [Medicare Severity-DRG]. Hospitals are not universally tracking all relevant ICD-9 procedure codes unless they are tied to a specific payment, so they often miss capturing some of the actual devices they are using because they are not.

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Sheri Dodd added:

The motivation is pretty small. If there is no additional payment, [hospitals] aren't motivated to code for it. Hospitals have a difficult time tracking the use of one device versus another or the use of a device versus no device in a systematic way. For a P&T committee to review evidence-based medicine to analyze patient outcomes and associate those outcomes with specific devices, those data are going to be really poor.

Reimbursement Practices May Create A Cost Barrier to New Technology Adoption

The rate of payment per case established by a Medicare DRG is intended to cover all the services provided by the hospital, including reimbursement for the cost of devices used in surgery.⁴ “Medical devices may add cost to a procedure, but there is rarely an incremental payment for a device under a DRG,” noted Christine Maroulis. Although prices for devices have been increasing, Medicare’s per-case payments for some surgical admissions have been decreasing.⁴ Manufacturers’ prices for artificial knees and hips have risen by an average of 8% per year.⁴ However, within a five-year period, Medicare’s per-case payments to hospitals for hip implant procedures fell by more than 9%.⁴ In 2006, a proposal was also made to reduce reimbursements for hip and knee replacements by 10%.⁴

The fixed-payment rate provided by DRG or APC, therefore, places pressure on hospitals to make economical choices about the technologies and services they provide.¹⁴ Because the CMS reduces all hospital charges to costs by the same ratio, hospitals receive a relative underpayment for more costly procedures and a relative overpayment for those that involve lower-cost supplies.¹⁴ Hospitals receive a fixed rate of payment and thus have an incentive to hold down medical device costs for procedures and to limit length of stay per admission.¹⁴ Hospitals are also underpaid for procedures when they do not fully account for medical device charges in their bills or when they do not correctly code and charge for the actual number of units used in a medical procedure.

Fixed-rate, prospective payment systems, therefore, discourage the use of new, higher-cost technologies that might increase quality of care or improve patient outcomes.¹⁴ Hospitals have little financial incentive to make use of higher-cost technologies that are more cost effective or provide better outcomes beyond patient discharge.¹⁴ Sheri Dodd explained, “Sometimes the benefit of a device is in the patient’s getting out of hospital early, therefore enabling the patient to go back to work sooner. Obviously, this is of great value to the patient and to the employer but not necessarily to the hospital.” Christine Maroulis added, “Everyone will agree that the value to the patient in this situation is tremendous, but neither the hospital nor the payer is terribly motivated to pay for that, because it’s not really in either of their direct financial interests.”

To ensure the adoption of new technologies and procedures, it is therefore important that appropriate costs be carefully integrated into established prospective payment systems.¹⁴ Medicare has considerable discretion in setting initial payment rates for new technologies and procedures.¹⁴ How-

ever, if the CMS assigns a new device to a particular DRG, APC, or physician fee schedule with a payment rate that is too low or that does not cover the cost of a new technology, health care providers and suppliers lose money.¹⁴ Economic losses discourage the use of new technologies and lessen the incentive for manufacturers to innovate.¹⁴ Cochlear implant surgery was assigned a DRG with too low a rate of payment because none of the other procedures in the same DRG category involved an implanted device.¹⁴ This might have severely curtailed the dissemination of this new medical technology.¹⁴ As with technologies outside the field of health care, there is a tension between affordability and value and driving innovation to fulfill the market’s unmet needs.

Reimbursement coding, coverage, and payment processes are complicated and time-consuming and present difficult challenges.¹⁴ As health care costs rise, reimbursement processes will continue to evolve and new challenges will become apparent.¹⁴ Continued medical innovation will occur only if proper coding, timely coverage, and fair payment are inherent in reimbursement policies.¹⁴ The Medical Payment Advisory Commission (MedPac), which was established to advise Congress on matters affecting the Medicare program, has addressed these reimbursement dilemmas.⁴ This committee has studied pricing for expensive items such as stents, implants, and pacemakers.⁴ Members of MedPac recognize that it is not feasible for Medicare (or private health plans) to designate the use of any particular device, because this would be equivalent to practicing medicine illegally.⁴ MedPac has instead recommended that hospitals partner with their medical staffs to standardize the use of medical devices and to secure large discounts from suppliers to control costs.⁴

Physician Preferences May Discourage Cost Containment for Medical Devices

Because the “per-discharge” costs of medical devices and the costs of other physician preference items are increasing, hospitals are directing greater attention to product selection and standardization.⁴ Christine Maroulis observed:

Clearly, escalating costs and decreasing reimbursements are driving this behavior. We have also seen a proliferation of new devices coming into the hospital. For example, surgeons have different opinions on which devices they like to use for their patients, and for years, the hospitals conceded to the surgeons’ preferences. In the area of women’s pelvic health, a hospital may have five different suburethral slings on the shelf. The hospitals are starting to realize that this might not make any financial sense at all.

Gaining control of the costs associated with a hospital’s supply chain presents special challenges, because the most expensive supplies (representing up to 61% of total costs) are items for which physicians have strong preferences.⁴ These items include hip and knee implants, cardiac stents, and the mechanical devices used in spine surgery.⁴

Although hospitals bear the cost of these devices, physicians or surgeons determine which device should be used for a particular procedure or patient.⁴ The doctors’ decisions are often based on factors unrelated to cost, such as the clinical evaluation of a particular patient, personal experience with a

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product, and a relationship with or trust in the manufacturer.⁴ Furthermore, in 2007, physicians performing hip operations were reimbursed about \$2,000 regardless of which device they used, whereas a hospital had to pay device costs between \$2,000 and \$10,000, depending on the brand of hip implant chosen.⁵ These factors can create a chasm between a hospital's cost-containment goals and physician or patient preferences.⁴

However, a shift may be occurring in this paradigm. Sheri Dodd explained:

We can say in general terms that this is changing. The surgeon and department chairs are seeing restrictions and a need for prioritization in terms of which technologies and innovations are brought in unchallenged. Therefore, we are anticipating, at launch of some products, that there will be a review by the hospital's new technology committee, and I frankly think that we'll welcome that, assuming a fair and robust review process, because if we are generating evidence to support our product value, providers, purchasers, and patients will receive the benefit.”

Gaining control of the costs associated with a hospital's supply chain presents special challenges, because the most expensive supplies ... are items for which physicians have strong preferences.

Physician preferences may discourage the involvement of doctors in the medical device standardization process.⁴ Physicians may withhold participation to express resistance to the concept of product standardization, especially when it appears to be imposed and overseen by management.⁴ Unfortunately, however, without their participation, the process is not valid.⁴ If standardization does not produce a rigid product formulary imposed and enforced by non-clinicians, physicians may be more willing to be involved in the process.⁴ Physician cooperation may be facilitated by a clinical resource specialist with clinical experience (often a nurse practitioner) who can rely on practical knowledge and competence.⁴

Because it is sometimes problematic for hospitals to dictate product choices to physicians, some organizations are instead trying to influence physicians' decisions by creating incentives.⁴ These inducements are offered by hospitals to motivate physician involvement and to align them more closely with the financial interests of the hospital with respect to supply-chain decisions. Such creative incentives include improvements in patient care and investments in new technologies and capital equipment.⁴

Consideration has also been given to “gain-sharing” by physicians, but this approach is often dismissed because of the possibility of a conflict of interest.⁴ It has also been found that nonfinancial incentives can have as strong or a stronger impact on physician behavior than financial incentives.⁴ Alignment of physicians with hospitals' interests in terms of standardizing medical devices and other physician preference items may be a primary factor that distinguishes successful hospitals from those struggling to remain viable.⁴

Potential Conflicts of Interest And the Influence of Manufacturers

Potential conflicts of interests have important consequences not only for the individual physicians but also for hospitals, patients, and manufacturers.¹⁵ In the device industry, an ongoing dialogue between clinicians and manufacturers is essential to optimize products, instruments, and surgical techniques.² The early development of a medical device typically requires that a clinician be an important part of the development team.¹⁵ Physicians play an influential role in identifying and defining an unmet clinical need, generating early concepts and design solutions, and validating prototypes.¹⁵ Such involvement promotes a thorough understanding of a specific device by the clinician.¹⁵ Physicians are integral to the entire process that makes the development and introduction of new devices possible.¹⁵

A conflict of interest may occur because manufacturers offer consulting fees and honoraria to physicians, which may provide a financial incentive for the physician to select the company's products.⁴ Manufacturers also financially sponsor physician programs that support professional skills, medical research, and resident or fellow education.¹⁵ Additionally, industry provides grants that support educational, scientific, independent, or policymaking meetings that promote scientific knowledge.¹⁵ This activity has received attention by regulators and the media, resulting in regulatory efforts to constrain incentives.⁴

The trade organization for medical device manufacturers (AdvaMed) has published guidelines for their dealings with health care providers.¹⁵ These guidelines address the potential ethical and legal implications of manufacturer–physician relationships and the potential appearance of impropriety with regard to federal law.¹⁵ Manufacturers must be sure that they pay only fair market value for new concepts provided by physicians and that consulting fees are clearly related to the value of a physician's contribution.² The medical device industry also recognizes that adherence to ethical standards and compliance with applicable conflict-of-interest regulations is critical to ensuring an ongoing mutually productive relationship with health care professionals.¹⁵

The close relationship between manufacturers and clinicians has long frustrated hospitals' efforts to control supply costs.⁴ Many supporters of standardizing medical devices within hospitals view the physician–vendor relationship as responsible for a “huge breakdown in the system.”⁴ Manufacturers are viewed as having long influenced physicians' selection of products as well as product pricing.⁴

Some hospitals use tactics to gain greater control over manufacturer involvement that preserve the benefits they provide but that curtail vendor influence on decision making.⁴ Some hospitals control access to their facilities and set boundaries on vendors' access to physicians; for example, vendors might need hospital certification and a preapproved appointment to enter the facility.⁴ However, hospitals cannot control clinicians' relationships with vendors outside their facility.⁴

Although vendors have been heavily criticized for their perceived attempts to influence clinicians' choices, their value in the process is nevertheless well recognized.⁴ Maintaining an appropriate balance between the costs and benefits of the

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physician–supplier relationship is important.⁴ The relationship between physicians and manufacturers may change with more aggressive standardization efforts as well as with the introduction of creative physician incentives offered by hospitals.⁴

Alternative Models That Support Cost Containment

Value Analysis Teams

Many hospitals are developing value analysis teams (VATs) to evaluate new technology and to justify the purchase and expense of these products.² These teams facilitate decision making and standardization regarding medical devices and other supplies.⁴ The establishment of VATs is growing despite the fact that they face unique challenges in determining product equivalencies for medical devices that P&T committees do not confront when they are evaluating drugs.⁴ VATs, like P&T committees, are designed to assess products in terms of patient outcomes, safety, and relative costs.⁴ Such assessments of comparability are then used to make contracting and other tactical decisions about product equivalencies.⁴

However, VATs are very diverse in their composition and function, so the VAT model has not become standardized in a way that can be easily adopted throughout all health care facilities. Sometimes hospitals use a group-purchasing organization to assemble influential clinicians for the process; in other instances, VATs are created and work within an individual facility.⁴ VATs also differ from P&T committees in terms of permanency. Some teams are *ad hoc* committees formed at the end of a contract period, or the teams might be created to evaluate new products as they are introduced into the market. Other teams are permanent committees that are responsible for a particular product category.⁴

Other Models

Hospitals can follow other models to standardize or limit medical device purchases to certain manufacturers or products (the *formulary model*) or to set price ceilings for certain categories of items (the *payment cap model*).⁴ Different decisions are required for these models in terms of product choice, price, and equivalency.⁴

Formulary Model. The formulary model may be more difficult than the payment cap model to institute because of the potential for physician resistance to dictates by upper management.⁴ Because this model limits physician choice, it places a greater burden on physicians to adjust to restricted options.⁴ Consequently, physicians might need to change their practice decisions to comply with the availability of products on the formulary, or they might need to frequently request exceptions.⁴

Payment Cap Model. The payment cap model may be more feasible because it preserves physician choice but restrains manufacturer influence.⁴ It does not restrict particular products or manufacturers; instead, it restricts the prices paid for products in a particular category.⁴ This strategy relies on competitive pricing between manufacturers of similar products below a price ceiling established by the hospital for that item.⁴ This approach places the burden on suppliers to alter pricing strategies in order to satisfy hospital price ceilings.⁴

This model may therefore lessen the burden on physicians to change their preferences, because it preserves a wider range of product choices for them.⁴ However, if vendors do not agree to meet a price ceiling, a physician's product choice may be restricted when that product is no longer purchased by the facility.⁴ Therefore, physicians might still be requested to agree to product equivalencies, and thus they must be committed to abandon their preferred product choice if its price is not compliant.⁴ Hospitals have little chance of implementing cost reductions and decreasing their dependence on suppliers without this commitment.⁴ Hospitals that use a payment cap strategy have reported success, and they have noted that, ultimately, vendors tend to comply with the established price ceiling.⁴

Group Purchasing Organizations. Hospitals are mindful that when they can choose among competing products, they may have more opportunities to negotiate with vendors for better prices.⁴ Yet hospitals seem to differ in their ability to negotiate prices for medical devices, because costs for the same device can vary dramatically.⁴ In a survey of 100 hospitals, the prices for the same device ranged between \$2,000 and \$9,000.⁴

Many hospitals in the U.S. have tried to gain leverage in negotiating and controlling supply expenses through creative contracting with manufacturers, either through group-purchasing organizations or local contracting bodies.⁴ Manufacturers often offer more favorable pricing exchange for the commitment of an organization to purchase a specific volume of a product—a process known as “contract compliance.”⁴ However, whereas hospitals can commit to purchase a specified volume of bandages and syringes, this type of arrangement is not usually possible for medical devices, because physician preferences vary widely.⁴

Value-Added Manufacturer Services May Assist in Decision Making

Medical device manufacturers can help hospitals by offering value-added services in numerous areas. Companies that have a value-added approach rather than a single-minded focus on product sales might also gain a competitive advantage.⁵ Manufacturers often provide physicians and clinical support staff with specialized knowledge and train them in the selection and use of products for specific patients.⁴ Some companies even offer on-site expert advice and technical assistance with instrumentation and calibration during procedures in the operating suite.⁴ Vendors often assist with a hospital's inventory management, an invaluable service for products with a short shelf life.⁴ Many vendors deliver products on a “just-in-time” basis on the day surgery is scheduled.⁴ Vendors also help hospitals keep current by providing updates on FDA approval status and new product availability.⁴ Most hospitals and their clinical staff consider these services to be essential, recognize their dependence on them, and therefore want to maintain vendor involvement to some degree.⁴

It has been suggested that manufacturers provide additional value by becoming accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).⁵ Accreditation and pay-for-performance initiatives could be supported by suppliers that link their physical products to factors such as reduction in mortality, complications, and average length of

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stay, as well as improvements in outpatient revenue, cash flow, occupancy, and accounts receivable.⁵ Value and service packages might also go beyond supporting the physical features of a product and might aim to improve outcomes for postoperative infections, ulcers, cardiac arrest, gastrointestinal bleeding, and urinary tract infections.⁵ Other factors to consider are the time, expense, and convenience associated with training, maintenance, space requirements, ease of use, portability, access, storage, and the need for refrigerating or freezing the product in question. Sheri Dodd remarked, "As a smart manufacturer, we would have our submission packages to a hospital's new technology committee try to address why our product would have a minimal negative impact on an operating room or a system." Accreditation status and value-added services may be a means by which hospitals can base their choice of vendor whenever feasible.

Emerging Trends

Whether all hospitals and systems will adopt a VAT or another type of in-house analytical committee remains to be seen.⁴ Group purchasing and consulting firms have created an industry around value analysis and product standardization.⁴ These services are increasingly being offered to hospitals as an alternative to internal product assessment.⁴ However, Dr. Nash sees these groups as not being "realizers." He stated that "it's a third-party action and a technology assessment rather than a P&T committee review, which would be more practical."

The role of agencies such as the FDA or the Agency for Healthcare Research and Quality (AHRQ) might also be expanded to provide uniform standards, guidance for product evaluation, and regulation of off-label use.⁴ However, physicians believe that national standards are not an adequate substitute for the local determination of product equivalencies.⁴ It is thus uncertain whether determinations of product equivalencies made by a governmental agency would be widely accepted.⁴

Rather than an increasing influence by regulatory agencies, patients are beginning to have more input in determining their medical care. Although physicians, hospitals, device manufacturers, and insurers have traditionally been the primary players in determining medical device usage, patients are playing an increasing role as they learn more about new technologies.¹³ Because of the ability to access information sources such as the Internet, patients are becoming more educated about choices of manufacturers, surgeons, products, and procedures.² Patients are acquiring more power in the health care supply chain, and their preferences are influencing companies, physicians, and hospitals.⁴

Patients have become increasingly knowledgeable about—and expect minimally invasive (and, in some cases, noninvasive)—procedures that minimize scars and soft-tissue trauma and allow a more rapid return to normal life.^{2,9} Companies are working diligently to develop techniques and products that support such procedures.² Christine Maroulis notes:

There's clearly a shift in the population. Patients are increasingly demanding minimally/noninvasive procedures, and they will actively seek hospitals and doctors who will perform them. We've seen

this trend beginning with baby-boomers, and we certainly expect it to continue with generations X and Y. For example, few women will accept an open hysterectomy as their only option in light of the myriad of alternative procedures available to them which are either minimally invasive, or—in some instances—uterus-sparing, which enable them to resume their normal, daily life in a matter of hours or days, as opposed to weeks. For us, the patient is clearly driving most of our innovation.

Patients are acquiring more power in the health care supply chain, and their preferences are influencing manufacturers, physicians, and hospitals.

Patient spending accounts and high-deductible health plans may also cause patients to become more vocal in expressing their preferences for certain products or medical procedures.⁴ They are often not as concerned about expense, because a high-cost medical device, unlike a drug, is a one-time expenditure that will often last the remainder of their life.² Patients are driving demand, and a hospital's failure to offer the products and procedures they expect may mean diminished access to those patients.⁹ Christine Maroulis observed:

Most hospitals that are offering these really neat, innovative, minimally invasive surgeries are often doing it partly as a public relations strategy. It's possible that these procedures won't be financially attractive to them, but they often adopt them because they acknowledge that they will likely attract more patients and their families to the hospital because they offer these options for women.

The trend of an increasing influence of patient demands also raises debate about direct-to-consumer (DTC) advertising by manufacturers.⁴ Spending for DTC advertising of medical devices grew from almost nothing in 1996 to nearly \$50 million in 2005.⁴ More than 25% of medical device manufacturers now report engaging in DTC campaigns.⁴ As this practice attracts more controversy, it may trigger increased regulatory intervention that could inhibit commercial influence on patient preferences.⁴

Another emerging trend is the integration of other therapies, such as drugs or biologics, with medical devices to offer promising new products to surgeons.⁹ Dr. Vogenberg observed, "We are seeing an explosion now in biotechnology and nanotechnology that will really expand during the next 5 to 10 years that is based on research done in the late 1990s, so there is really a logical flow to how things move through the intellectual pipeline." Sheri Dodd also commented:

Drug-device combinations, biosurgicals, regenerating tissue, and other breakthrough innovations are the future for a lot of [devices], which will naturally follow development pathways that are similar to pharma programs (i.e., phase 1, 2, and 3 [clinical trials]) for safety and efficacy, with economic evaluation generated in real time.

Next-generation cell therapy practices are expected to combine allogenic and genetically modified cells with advanced bio-

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materials designed to support cellular survival and engraftment.⁹ Joints and joint surfaces may eventually be regrown and replaced with biotech products instead of mechanical implants.² Miniaturization and telemetry already make it possible for physicians to monitor patients remotely, and advances in health information systems promise to improve the integration of care delivery.¹

Areas for Improvement in Medical Device Review and Procurement

Without question, an alignment of manufacturer, hospital, practitioner, and patient interests will be necessary to improve the purchase and use of medical devices. The medical device industry invests heavily in new techniques and technology, research, product development, reimbursement, and patient access.⁹ Alignment of interests can occur through close working relationships with manufacturers that provide access to hospital executives and purchasing departments to educate them about the impact of technology investments on cost-benefit and improved patient outcomes.⁹ Better reimbursement mechanisms for new procedures or technologies may also emerge if doctors, hospitals, and manufacturers unite and lobby for them.⁹

Hospitals and practitioners can also take a leadership role in improving practices for monitoring and benchmarking clinical outcomes and disseminating the information necessary for evidence-based technology assessments.⁹ More sophisticated information systems are being developed that link products to cost, outcomes, and safety, but widespread adoption requires establishing standards for systematic data collection as well as specially trained staff members to conduct evidence-based studies that incorporate cost-benefit and cost-effectiveness analyses.⁴

With the availability of more postmarketing surveillance data, independent organizations can conduct technology assessments to identify the medical technologies that have pitfalls and those that are truly beneficial and safe.⁸ Such assessments will educate both health care professionals and patients, and they may also motivate researchers to address unanswered questions.⁸ An expanded, more informed understanding of new medical devices is expected to enhance health outcomes.

Progress toward the establishment of a more standardized medical device review process is represented by the formation of the Association of Healthcare Value Analysis Professionals (AHVAP).⁴ The widespread use of VATs or other internal assessment committees may achieve the ideal goal of preserving quality and a diversity of options while controlling the costs of devices. In order to protect patient interests and to prevent undue emphasis on costs, it may also be desirable to designate a patient advocate to participate in the review process. Christine Maroulis noted, "Having a patient advocate would be a wonderful addition to these committees. I frequently meet with hospital committees, and I've rarely seen a patient advocate as a voting member of the committee. Ideally, the patient's interests are prioritized in these decisions."

Collaboration between physicians, hospitals, industry, insurers, regulators, and patients has long been essential to the development of medical devices that have eased suffering,

prolonged survival, and improved quality of life for patients.¹⁵ All contributors should view themselves as strategic partners and work together for this common purpose.

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